Imported food risk advice

Arsenic in human milk and human milk products

Context of this risk advice

- Human milk means expressed milk collected from lactating women to be fed to infants that are not the biological infants of the women supplying the milk.
- Human milk products means products derived from human milk that have been specially formulated to meet the specific nutritional needs of infants such as fortifiers and formula.
- The level of risk for this hazard in human milk and human milk products was determined assuming that the most vulnerable category of infants (preterm infants in hospital neonatal intensive care units) would be receiving the products.

Nature of the hazard

Arsenic is a metalloid that occurs in various inorganic and organic forms. It is found in the environment due to both natural occurrence and anthropogenic activity such as mining and industrial processes (WHO 2011). The main source of human exposure to arsenic is from the consumption of contaminated water and seafood. Other sources include inhalation of ambient air and cigarette smoke (EFSA 2009).

Arsenic is highly toxic in its inorganic form, and long term exposure from food and drinking water has been associated with cancer, skin lesions, developmental effects, cardiovascular disease, neurotoxicity and diabetes (WHO 2011).

Presence in human milk

Arsenic has been detected in human milk samples from Asia, Africa, Europe, North America and the Middle East (Bansa et al. 2017; Bassil et al. 2018; Björklund et al. 2012; EFSA 2009; Rebelo and Caldas 2016; Sakamoto et al. 2012). The majority of studies report the presence of arsenic in human milk as total arsenic, without analysis of the specific form, which could lead to an overestimation of exposure to inorganic arsenic. Many studies are based on a small number of samples. The analytical methods and associated limits of detection and quantification vary between studies.

While arsenic has been detected in human milk samples worldwide the concentrations are generally low, with urine being a much more efficient arsenic excretion route than lactation (Rebelo and Caldas 2016). Studies indicate that infants who are exclusively breast fed generally have lower arsenic exposures than formula fed infants, both in areas with high levels of arsenic in drinking water and in areas with lower levels (Carignan et al. 2015; Carignan et al. 2016; EFSA 2009; Fängström et al. 2008).

Adverse health effects

The World Health Organization (WHO) reports that few, if any, adverse effects have been associated solely with consumption of human milk containing background levels of environmental chemicals. This is in contrast to the established evidence that human milk and the practice of breast-feeding confer significant health benefits to infants (WHO Undated).

Epidemiological studies have reported associations between chronic ingestion of inorganic arsenic and a range of adverse health effects. The Joint Food and Agriculture Organization (FAO)/WHO Expert Committee on Food Additives (JECFA) has concluded that the strongest evidence of a causal association between inorganic arsenic and effects in humans is for skin lesions and cancers of the skin, urinary bladder and lung (WHO 2011). In 2011, JECFA calculated the lower limit on the benchmark dose of inorganic arsenic associated with a 0.5% increased incidence of lung cancer ($BMDL_{0.5}$) to be 3 µg/kg body weight (bw)/day.

A recent review paper estimated mean arsenic intakes from human milk for infants in the USA, Japan, Portugal, Bangladesh and India, based on concentration data published in the scientific literature and assuming that all arsenic detected was inorganic arsenic (Rebelo and Caldas 2016). Average total arsenic intakes among breastfed infants in Lebanon have also been estimated recently, based on a small number of human milk samples (Bassil et al. 2018). In all cases the estimated exposures were below the $BMDL_{0.5}$ of 3 µg/kg bw/day established by JECFA. A recent study of mining communities in Ghana where high levels of environmental arsenic contamination has been reported found that estimated infants' exposure to total arsenic from human milk ranged from 1.05 – 7.05 µg/kg bw/day, with mean levels below 3 µg/kg bw/day (Bansa et al. 2017).

The European Food Safety Authority (EFSA) calculated a range of benchmark dose lower confidence limit values for a 1% increased incidence ($BMDL_{01}$ values) of skin lesions and cancers of the lung, skin and bladder ($BMDL_{01}$ 0.3 – 8 µg/kg bw/day) (EFSA 2009). EFSA found that infants below 6 months of age fed on only human milk, or on cows' milk formula prepared with water containing arsenic at the average European concentration, have the lowest estimated dietary exposure to inorganic arsenic compared with older children or adults. Estimated exposure from cows' milk formula was three times higher than that from human milk, but exposures were below the range of $BMDL_{01}$ values for both breast fed and formula fed infants.

Overall the available evidence indicates that in the majority of groups studied, estimated dietary arsenic exposures of breastfeeding infants are below the BMDL values identified by JECFA and EFSA.

Risk mitigation

Australian and overseas milk bank guidelines do not include recommendations to specifically screen donors for levels of arsenic (Hartmann et al. 2007; HMBANA 2015; NICE 2010). However, some guidelines recommend consideration of whether a donor has any significant exposures to environmental or chemical contaminants that can be expressed in human milk, through for example contamination of the local water supply (NICE 2010).

General screening would be expected to be sufficient to take into account any potential risks of there being a significant source of exposure to arsenic in imported human milk and human milk products.

The American Academy of Pediatrics notes that the pooling process with donor milk makes it very unlikely that non-infectious contaminants will represent a significant exposure risk (Committee on Nutrition, Section on Breastfeeding, Committee on Fetus and Newborn 2017). Pooling of human milk from multiple donors is common practice amongst many human milk banks, however some milk banks only pool milk from individual donors (Haiden and Ziegler 2016). The Australian Red Cross milk bank pasteurises human milk in single donor batches (Australian Red Cross 2018).

Evaluation of uncertainty

There is uncertainty as to the concentrations and forms of arsenic that may be found in human milk and human milk products. This would be expected to vary depending on the geographic location of the individuals donating milk, and whether they may have any risk factors for high levels of exposure.

Many studies of the presence of arsenic in human milk are based on a small number of samples. The analytical methods used vary between studies, with differing limits of detection and quantification. The majority of studies report the presence of arsenic in human milk as total arsenic, without analysis of the specific form, which could lead to an overestimation of exposure to inorganic arsenic.

Risk characterisation

Arsenic concentrations in human milk are generally low, and studies indicate that infants who are exclusively breast fed generally have lower arsenic exposures than formula fed infants, both in areas with high levels of arsenic in drinking water and in areas with lower levels.

A recent review found that estimated exposures to inorganic arsenic from human milk in almost all identified published studies were below the BMDL for a 0.5% increased incidence of lung cancer established by JECFA. Similarly, an EFSA evaluation found that estimated dietary arsenic exposures of European breastfeeding infants were below BMDL values for a 1% increased incidence of skin lesions and cancers of the lung, skin and bladder.

On the basis of the available evidence FSANZ concludes that arsenic in imported human milk and human milk products is unlikely to present a potential medium or high risk to public health and safety.

This is consistent with WHO advice which notes that few if any adverse effects have been associated with consumption of human milk containing background levels of environmental chemicals, in contrast to the established evidence that human milk confers significant health benefits to infants.

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